



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Daniel FLAMMANG

Appl. No. 09/586,942

Confirmation No.: 6577

Filed: June 2, 2000

For: ELECTRODE LEAD WITH
MULTIPLE BRANCHES (as
amended)

Art Unit: 3762

Examiner: F. OROPEZA

Atty. Docket No. 31512-172579

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SUPPLEMENTAL APPEAL BRIEF

Sir:

This Brief Supplements the Appeal Brief, which the Appellant filed on November 25, 2002 (in triplicate). Accordingly, this Supplemental Brief incorporates some of the parts of the previously-filed brief as noted. In view of the Examiner's change of the rejections, the Status of the Claims, Status of Amendments and Issues sections have been modified and Appellant's arguments address the new ground of rejections raised after prosecution had been reopened after the initial Appeal. Appellant now presents herewith this Supplemental Appeal Brief in triplicate pursuant to 37 C.F.R. § 1.192.

(1) REAL PARTY IN INTEREST

The Assignee of this Application, and thus the real party of interest in this Appeal is as stated in the Appeal Brief filed November 25, 2002.

(2) RELATED APPEAL AND INTERFERENCES

No Appeal or Interference is known to Appellant, the Appellant's legal representative or Assignee which would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

(3) STATUS OF CLAIMS

The Application was filed with claims 1-12, which were canceled and replaced with new claims 13-25 in the Amendment filed February 28, 2002. Claim 13 was cancelled and replaced with amended claim 20 written in independent claim form and claims 14-17 and 19 were amended in the Amendment After Final Rejection filed April 12, 2002, which was indicated as being entered in the Advisory Action dated August 27, 2002.

After an Appeal Brief was filed on November 25, 2002, the Examiner withdrew the finality of the final Office Action thereby reopening prosecution of this application. Appellant filed an Amendment on June 10, 2003 amending claims 20 and 23 and adding claim 26. The Examiner finally rejected claims 14-26 in a July 22, 2003 Office Action, which added U.S. Patent No. 4,726,379 to the previous combination. On October 22, 2003, Appellant submitted an Amendment After Final Rejection that was not entered by the Examiner. A Request for Continued Examination was filed to enter the Amendment After Final Rejection that was filed on October 22, 2003 to clarify the function of the structure of claim 20.

In response, the Examiner issued a non-final Office Action rejecting claims 14-26 with the same combination of references as in the July 22, 2003 Office Action. Thus, claims 14-26 have been rejected twice.

Claims 20, 14-19 and 21-26 are appealed and set forth in the Appendix to this Brief.

(4) STATUS OF AMENDMENTS

The Amendment After Final Rejection filed on October 22, 2003 was entered upon Appellant's Request for Continued Examination, including the fee, as indicated in paragraph 1 of the January 6, 2004 Office Action. Accordingly, claims 20-26 are pending and rejected by the Office Action dated January 6, 2004.

(5) SUMMARY OF THE INVENTION

The Summary of the Invention is as in the Appeal Brief filed November 25, 2003.

(6) ISSUES

The issues on appeal are as follows:

I. Whether claims 14, 19-24 and 26 are properly rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,855,592 to McGee et al. (hereinafter referred to as "McGee") in view of European Patent Application No. 0 601 328 to Ljungström (hereinafter referred to as "Ljungström") and U.S. Patent No. 4,726,379 to Altman et al. (hereinafter referred to as "Altman")?

II. Whether claims 15-18 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee in view of U.S. Patent No. 5,834,031 to Cookston et al. (hereinafter referred to as "Cookston"), or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over McGee in view of Ljungström and Altman and further in view of Cookston et. al.?

III. Whether claim 25 was properly rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee in view of U.S. Patent No. 4,664,120 to Hess, or in the alternative, under 35 U.S.C. § 103(a) over McGee in view of Ljungström and Altman and further in view of Hess?

(7) GROUPING OF CLAIMS

An independent defense is presented in connection with independent claim 20. However, no independent defense is presented with respect to depending claims 14-19 and 21-26. Accordingly, the dependent claims stand or fall together with the independent claim.

(8) ARGUMENT

I. CLAIMS 14, 19-24 AND 26 ARE PATENTABLE OVER MCGEE, EITHER ALONE OR IN COMBINATION WITH LJUNGSTRÖM AND ALTMAN UNDER 35 U.S.C. §§ 102 (b) or 103(a), RESPECTIVELY

Appellant will show that McGee alone does not anticipate the claimed invention under 35 U.S.C. § 102 (b) and that the combination of McGee in view Ljungström and

Altman does not render obvious the subject matter of independent claim 20 under 35 U.S.C. § 103(a).

I. A. The Examiner's Position

According to the Action mailed January 6, 2004, the “characteristic of ‘unambiguously associated’ electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area.” The Action cites portions of McGee that are directed to pacing and then is silent as to the entire “wherein” clause following the recitation of the septal and lateral branches having an equal number of electrically conductive surface portions disposed thereon. It is this “wherein” clause that further describes the relationship of the unambiguously associated pairs of electrically conductive surface portions of the septal branch and electrically conductive surface portions of the lateral branch.

The Action admits that McGee does not disclose, teach or suggest lateral and septal branches, as claimed by Appellant under the alternative rejection of McGee in combination with Ljungström and Altman. Likewise, the Action admits that McGee does not disclose, teach or suggest a bipolar pacing mode using an anode and a cathode. The Action uses the teachings of Ljungström to suggest the claim septal and lateral branches; and the teachings of Altman of a bipolar mode of operation that occurs in a heart.

B. The Appellant's Position

In addition to the arguments set forth in the November 25, 2002 Appeal Brief, the following arguments are presented to address the change in the rejection to the claims.

As explained in Section 5 of the Appeal Brief, the invention is directed to an electrode arrangement for endocardial discharge of defibrillation pulses in the atrium or a ventricle of the heart. As shown in Fig. 2b of the instant application, the dash-dotted lines joining electrodes (30 and 32) of the septal branch (14) to unambiguously associated electrodes (30 and 32) of the lateral branch clearly illustrate the layers defined in the atrium by the associated electrode pairs. Page 9, lines 17-27, page 3, line 25 page 4, line 3 and page 5, lines 10-25 of the instant application define what is meant by “unambiguously associated” electrodes. Claim 20 was amended to clarify the structure of the claimed electrode arrangement and positively recites that “each electrically conductive surface portion of the septal branch is unambiguously associated in pairs with an electrically conductive surface portion of the lateral branch” and that “each pair is activated in such a way that the two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation.” As a result of this claimed structure, it is possible for electrodes to be positioned on mutually oppositely disposed side walls of the heart and for the electrodes to be actuated, in bipolar mode so that unambiguously associated electrodes (in pairs) can serve as an anode and a cathode for the discharge of voltage pulses to the myocardium (cardiac tissue) of the atrium. That is, the electrode arrangement according to the invention can assume positions in the heart so that associated electrodes in the septal and lateral branches define layers starting from the transition of the heart into the atrium thereof, thereby subdividing the atrium of the heart in parallel successive relationships, as explained on page 5, line 26 through page 6, line 3 of the instant specification. As a result of this claimed structure, a defibrillation

effect with an extremely low level of stimulation energy and a defibrillation which can be substantially pain-free for the patient can be provided.

Even if the characteristic of “unambiguously associated” electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area, as suggested by the Examiner, nowhere does McGee disclose, teach or even suggest that its electrodes are stimulated in pairs wherein each pair is actuated in such a way that two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation, thereby defining a layer in the atrium of the heart. Further, McGee does not disclose, teach or even suggest electrodes of different branches being stimulated simultaneously in pairs to form a stimulation layer through the heart, as claimed by Appellant.

On the contrary, McGee is directed to applying pacing signals from different electrodes at different times (column 4, lines 18-19 of McGee). McGee does disclose the inventive operation of the unambiguously associated electrodes in a bipolar mode where the unambiguous association defines a layer in the atrium of the heart and allows stimulation of the same by discharge of voltage pulses. At most, McGee discloses is an “iterative pattern” of pacing signals in column 7, lines 60-64. Nowhere does McGee disclose, let alone teach or suggest, stimulating electrodes simultaneously in pairs to divide cardiac tissue as claimed by Appellant. The anode and cathode mode of each pair, as described in the “wherein” clause of claim 20, enable the electrically conductive surface portions to divide the cardiac tissue as shown in Fig. 2b. Accordingly, McGee cannot anticipate the invention as set forth in independent claim 20 because McGee fails to disclose or inherently teach at least the above argued features.

The secondary reference to Ljungström is applied for its teaching of two branches of a defibrillation system. Nowhere does Ljungström state that each electrode of the septal branch is unambiguously associated in pairs with an electrode of the lateral branch wherein each pair is actuated in such a way that two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation as claimed by Appellant. It is this unambiguous association or pairing of electrodes disposed on different branches that enable the inventive electrode arrangement to achieve a defibrillation effect with an extremely low level of stimulation energy thereby providing a substantially pain-free defibrillation treatment. Nowhere does McGee or Ljungström recognize the advantage of unambiguously associating in pairs electrodes on different branches. Thus, both McGee and Ljungström, taken alone or in combination fail to teach the claimed invention, and both cannot provide the necessary motivation to modify the base reference to McGee, which teaches unipolar pacing.

The teachings of Altman are used in order to provide a reference that addresses a bipolar operation. However, Altman teaches a cardiac pacer using switched capacitor circuits for maintaining isolation between an atrial channel subsystem and a ventricular channel subsystem. That is, Altman teaches that each channel subsystem is independently operable for bipolar sensing. This is not the claimed invention, which recites that an actuated pair defines a layer spanning from the electrical conductive surface portion of the septal branch to the electrically conductive surface portion of the lateral branch thereby dividing cardiac tissue. Claim 20 recites that the anode is on one branch and the cathode is on another branch. Altman teaches away from this structure

and thus any modification of the base reference using the teachings of Altman cannot result in the claimed invention.

Nowhere does McGee provide a hint that its pacing method divides cardiac tissue. McGee teaches applying pacing signals to different regions of the atria and not the stimulation of electrodes in pairs to divide cardiac tissues thereby resulting in a better defibrillation device. It is the dividing of the cardiac tissue, which occurs as a result of the recited electrically conductive surface portions of the septal branch being unambiguously associated in pairs with an electrically conductive surface portion of the lateral branch that enables a defibrillation procedure to employ a lower current level than previously thought possible. Inasmuch as the known prior art, as well as explicit teachings from McGee, teach applying pulsing singles from different electrodes at different times, it is respectfully submitted that one of ordinary skill in the art would not have considered reconstructing the algorithm taught by McGee to that of the claimed invention. That is, there is no teaching, other than Appellant's own specification, that would motivate one of ordinary skill in the art to modify the algorithm taught by McGee. Further, McGee, Ljungström and Altman do not disclose, teach or suggest an electrode arrangement having two branches of electrodes where unambiguously associated pairs of the electrodes define a layer spanning from one branch to another branch thereby dividing cardiac tissue as claimed by Appellant. Accordingly, these references cannot be combined to achieve the claimed invention.

Nor do McGee, Ljungström and Altman disclose, teach or suggest a reason to associate electrodes of one branch with electrodes of another branch to achieve a defibrillation procedure involving a lower pain level for the patient. Accordingly, it is

respectfully submitted that there is no motivation to modify McGee's algorithm that pulses electrodes along a branch to stimulate a larger area of the heart into an algorithm that simultaneously actuates pairs of different branches (unambiguously associated) so that the two associated electrodes define slices of an atrium thereby allowing defibrillation with weaker currents than previously thought possible. As none of the applied references: McGee, Ljungström or Altman consider the amount of pain associated with current defibrillation procedures a problem, it is respectfully submitted that one of ordinary skill in the art would not have thought to modify the algorithm of McGee based on the teachings of McGee, Ljungström and Altman that are either silent or oppose the association of electrodes of different branches, as claimed by Appellants.

As stated by the Federal Circuit in Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 230 USPQ 416 (1986), "a single line in a prior art reference should not be taken out of context and relied upon with the benefit of hindsight to show obviousness." The numerous sections of McGee cited in the Office Action mailed January 6, 2004 are concerned with stimulating a larger area about a localized area and not with defining slices of the heart, as Appellant's claimed invention achieves as a result of its unambiguously associated electrically conductive surface portions (and recites in the "wherein" clause of claim 20). It is respectfully submitted that the general teachings of McGee, Ljungström and Altman fail to overcome the fact that those references lack the claimed unambiguous association of electrodes disposed on a septal branch with a respective electrode disposed on the lateral branch. That is, the general teachings of McGee, Ljungström and Altman do not by themselves teach Appellant's

claimed invention and is respectfully submitted that the Examiner is falling into the hindsight syndrome by using the Appellant's disclosure to improperly modify McGee.

At the time of Appellant's invention, one possible way to pace or defibrillation was to use one electrode (unipolar) or two electrodes on the same lead (bipolar). Currently, this is still the method employed in systems available for intracardia defibrillation. Nowhere does McGee provide a hint that dividing of cardiac tissues may occur due to its pacing, nor does McGee indicate that the pacing results in a better defibrillation device. It is the dividing of the cardiac tissue, which occurs as a result of the recited electrically conductive surface portions of the septal branch being unambiguously associated with an electrically conductive surface portion of the lateral branch that enable a defibrillation procedure to employ a lower current level than previously thought possible.

It is respectfully submitted that the Examiner employed impermissible hindsight reconstruction of the general disclosures of McGee, Ljungström and Altman to reject Appellant's invention. Clearly, none of the applied references discusses or suggests unambiguously associating an electrode of a septal branch with an electrode of a lateral branch. Thus, it is only the Appellant's own disclosure that recognizes the importance of unambiguously associating electrodes of a septal branch with electrodes of a lateral branch to provide effective defibrillation with a lower current, which is less painful for the patient.

II. CLAIMS 15-18 ARE PATENTABLE OVER McGEE IN VIEW OF COOKSTON, OR McGEE IN VIEW OF LJUNGSTRÖM AND ALTMAN AND FURTHER IN VIEW OF COOKSTON UNDER 35 U.S.C. § 103(a)

Cookston is directed to an apparatus and method for deflecting a tip of a lead or catheter. Nowhere does Cookston address, let alone disclose, teach or suggest an electrode lead having at least two branches including a septal and a lateral branch where electrically conductive surface portions disposed on one branch are unambiguously associated in pairs with a respective electrically conductive surface portion of the other branch. Moreover, nowhere does Cookston disclose, teach or suggest operating the same in the bipolar mode as claimed by Appellant. Accordingly, Cookston does not provide the teachings missing from the McGee or the above combination, as argued above. Accordingly, Cookston cannot render the claimed invention obvious.

III. CLAIM 25 IS PATENTABLE OVER McGEE IN VIEW OF HESS, OR, McGEE IN VIEW OF LJUNGSTRÖM AND ALTMAN AND FURTHER IN VIEW OF HESS UNDER 35 U.S.C. § 103(a)

Hess is applied for its teaching of a lead configuration that contains two atrium electrode branches 16 and a ventricle branch 15 to provide a multi-functional lead. Nowhere does Hess disclose at least two branches including a septal branch and a lateral branch. Moreover, Hess also fails to disclose, teach or suggest the unambiguously associated pairs of electrically conductive surface portions where one of the pair is disposed on one branch and the other of the pair is disposed on a second branch, let alone the claimed septal and lateral branches. Likewise, Hess does not disclose or teach or suggest operating the paired electrically conductive surface portions in a bipolar mode of

operation, as claimed by Appellant. Accordingly, Hess does provide the teachings missing from the above combination and cannot render the claimed invention unpatentable.

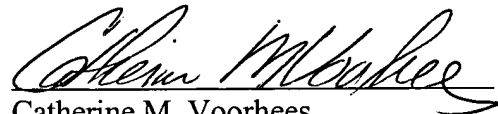
(9) CONCLUSION

For the foregoing reasons, it is respectfully submitted that independent claim 20 and its dependent claims 14-19 and 21-25 are patentable over McGee, either alone, or in combination with Ljungström, Altman, Cookston and/or Hess. Accordingly, the Examiner's rejection of these claims should be reversed.

The \$320.00 fee set forth in 37 C.F.R. § 1.17(c) was submitted with the Appeal Brief that was filed on November 25, 2002. Thus, no additional Appeal Brief fee is believed due. Should any additional fees be required, the Commissioner may charge the appropriate amount to our Deposit Account No. 22-0261 and notify the undersigned.

Date: April 7, 2004

Respectfully submitted,



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APPENDIX

Claim 14. The electrode arrangement according to claim 20, further comprising a sliding sleeve displaceable in a longitudinal direction of the electrode lead and actuating means for actuating the sliding sleeve wherein said central core is of one-piece construction in the form of a spring element and causes the branches to split apart when the actuating means moves the sliding sleeve toward the proximal end of the electrode lead.

Claim 15. The electrode arrangement according to claim 20, further comprising a sliding sleeve displaceable in a longitudinal direction of the electrode lead, means for actuating the sliding sleeve to split the at least two branches apart, and means for heating the memory member structure so that the shape of the memory member structure can change to maintain good contact between each branch and a wall of the atrium or the ventricle.

Claim 16. The electrode arrangement according to claim 15, wherein the memory member structure in at least one of the at least two branches is activatable simultaneously or after the actuating of the sliding sleeve, and a first branch assumes a shape as the septal branch and a second branch assumes a shape as the lateral branch for respectively assuming a septal position and a lateral position in one of the atrium and the ventricle of the heart.

Claim 17. The electrode arrangement according to claim 15, wherein at least one memory member structure, in at least one of the branches, experiences a predetermined change in shape by being heated above a predetermined temperature.

Claim 18. The electrode arrangement according to claim 17, wherein the memory member structure contains titanium.

Claim 19. The electrode arrangement according to claim 20, wherein the electrode lead is split into three different branches.

Claim 20. An electrode arrangement for the endocardial discharge of defibrillation pulses in one of the atrium and ventricle of the heart, comprising:

an electrode lead having an undivided proximal end, a distal end and a splitter from which at least two branches of the electrode lead extend to the distal end, each branch having a central core extending from the splitter of the electrode lead; and

a plurality of electrically conductive surface portions disposed on the at least two branches, said plurality of electrically conductive surface portions for being electrically connected by way of the electrode lead to an electrical pulse-discharging device at the proximal end of the electrode lead, wherein the at least two branches include a septal branch and a lateral branch, and the septal branch and lateral branch each have an equal number of electrically conductive surface portions disposed thereon, and each electrically conductive surface portion of the septal branch is unambiguously associated in pairs with an electrically conductive surface portion of the lateral branch, and

wherein each pair is actuated in such a way that two electrically conductive surface portions of a pair serve as an anode and a cathode in a bipolar mode of operation and each actuated pair defines a layer spanning from the electrical conductive surface portion of the septal branch to the electrically conductive surface portion of the lateral branch thereby dividing cardiac tissue resulting in a better defibrillation device.

Claim 21. The electrode arrangement according to claim 20, wherein the septal and lateral branch each has disposed thereon about 5 to 7 electrically conductive surface portions.

Claim 22. The electrode arrangement according to claim 20, wherein the electrically conductive surface portions are in the form of ring electrodes.

Claim 23. The electrode arrangement according to claim 22, wherein at least one of the ring electrodes are formed at the tip or distal end of at least one of the at least two branches.

Claim 24. The electrode arrangement according to claim 19, wherein the electrically conductive surface portions of each branch are respectively spaced approximately one centimeter from adjacent electrically conductive surface portions.

Claim 25. The electrode arrangement according to claim 19, wherein the at least two branches further includes a ventricular branch which is adapted to assume a position in a ventricle of the heart and has at least one ventricle electrode.

Claim 26. The electrode arrangement according to claim 20, wherein said central core is made of a memory member structure that enables good contact to be maintained between each branch and a wall of the atrium of the ventricle.